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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,507	10/04/2005	David Danvers Crossman	3003-1161	5480

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EXAMINER	
PANI, JOHN	
ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
10/27/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/520,507	CROSSMAN ET AL.	
	Examiner	Art Unit	
	JOHN PANI	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 8-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 8-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/22/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/7/2010 has been entered.

Claim Objections

2. Claims 4, 8, 9, and 20 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 4, 8, and 9 recite only "the lancet is spring-loaded to urge the lancet in a direction towards the opening in the housing". This limitation is included in claim 1. Claim 20 recites only "the cap holds the lancet against at least forward movement relative to the housing". This limitation is included in claim 1.

Claim Rejections - 35 USC § 112

3. Claims 1-5 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 recites "whereby the cap initially holds the lancet against forward movement relative to the housing under influence of said spring". It is unclear what claim limitation is "under influence of said spring." The claim has been interpreted to require that any previous structure could be "under influence of said spring".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 11, 12, and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 03/005907 to Koike et al. ("Koike").

Please note that US 2004/0243165 has been used herein as an English language translation for WO 03/005907, as US 2004/0243165 is a publication of the National Stage entry of PCT/JP02/07030. References to paragraph numbers below are made with respect to the US publication. It is noted that the drawing and reference numbers are identical for the two publications.

Koike teaches:

In reference to Claims 11 and 21

A blood sampling device comprising: a housing (1) having an opening (space 22" resides in), a lancet body (2) carrying a needle (20), the lancet body being movably mounted within the housing and arranged so the needle momentarily projects through the opening of the housing upon actuating the blood sampling device (see Figs. 12A-12C), a cap (12") having a first end (23) releasably attached to the lancet body and covering a tip of the needle (Fig. 16), the cap extending through the opening of the housing to a second end that is releasably attached to the housing by at least one locating member (e.g. 22" and the groove in 12" surrounding 22") on the second end that fits into at least one cooperating feature (distal walls of 1 and distal opening in 1) on an outer wall of the housing, the cap being twistable to release the at least one locating member from the at least one cooperating feature so the cap can be removed from the housing and the lancet body (see [0088]), the cap, the housing and the lancet body being arranged to prevent forward movement of the needle relative to the housing prior to removal of cap and actuation of the blood sampling device (see Fig. 16 with regards to the embodiment of Figs. 16-18C of Koike, it appears that the cap is somehow sealed to the body, as like all of the other embodiments, it requires twisting and pulling to remove the cap prior to use [0102] and the other embodiments include a physical attachment of the cap to the housing, e.g. [0063-0064], [0077], etc.; additionally, the force produced by driving means Y which forces 121 into 120 is not sufficient to force 120 off the casing, so it appears the cap prevents forward movement past the configuration shown in Fig. 18B until the cap is twisted off; finally, before the device of

Koike is attached to unit 4, the cap would prevent forward movement by preventing grasping the lancet and pulling it forward).

In reference to Claim 12

The blood sampling device of claim 1 (see above) wherein the cap is twistable to remove the cap's attachment to the housing and the cap's attachment to the lancet (see [0088]).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1, 2, 4, 5, 8, 10, 15, 16, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,487,748 to Marshall et al. ("Marshall") in view of Koike.

In reference to Claims 1, 4, 5, 8, 10, 15, 20, and 22

Marshall teaches a blood sampling device comprising: a housing (1, 2); a spring loaded (2) needle-carrying lancet (8) located within the housing, the spring urging the lancet for movement in a forward direction towards an opening at one end of the housing; a cap (20) releasably attached to said lancet adjacent said needle (17); and a trigger releasable latch (23, 12, etc.) to hold the lancet within the housing such that an exposed needle (19) cannot project through an opening at on end of the housing until

the latch is released by the trigger (9) (see at least col. 3), the cap extending to project from an attachment to said lancet through the opening (4) at one end of the housing (Fig. 1), the cap being twistable to release the cap from the lancet (col. 3 lines 10-15), wherein said trigger releasable latch and said lancet have respective opposed latch surfaces (12, 23) cooperable to retain said lancet in said housing until release of said latch, and said cap is adapted to hold the lancet in a position in which the lancet latch surface is spaced rearwardly of the latch surface of said trigger-releasable latch until said cap is detached from the lancet (see Fig. 1; note that the "opposed latch surfaces" have been interpreted to be the entire exterior surfaces of 12 and 23, and that when the device is in the pre-cocked version detailed in col. 2 lines 40-50, at least a portion of the surface of 23 would be spaced rearwardly with respect to a portion of the surface of 12). Additionally, at least the housing of Marshall is "under influence of the spring", because the spring exerts a force on the housing and the cocked lancet.

However, Marshall does not explicitly teach that the cap has at least one locating member fitting into at least one cooperating feature of outer walls of the housing, and the cap initially holds the lancet against forward movement relative to the housing, the cap being twistable to release the at least one locating member from the at least one cooperating feature such that the cap can be detached from the housing and from the lancet. Koike teaches a lancet device (see at least Fig. 16) in which the cap (12") has at least one locating member (22" and grooves in 12" surrounding 22") fitting into at least one cooperating feature (distal end of 1 in addition to distal hole in 1) of outer walls of the housing, whereby the cap initially holds the lancet against forward movement

relative to the housing (with regards to the embodiment of Figs. 16-18C of Koike, it appears that the cap is somehow sealed to the body, as like all of the other embodiments, it requires twisting and pulling to remove the cap prior to use [0102] and the other embodiments include a physical attachment of the cap to the housing, e.g. [0063-0064], [0077], etc.; additionally, the force produced by driving means Y which forces 121 into 120 is not sufficient to force 120 off the casing, so it appears the cap prevents forward movement past the configuration shown in Fig. 18B until the cap is twisted off; finally, before the device of Koike is attached to unit 4, the cap would prevent forward movement by preventing grasping the lancet and pulling it forward)), the cap being twistable to release the at least one locating member from the at least one cooperating feature such that the cap can be detached from the housing and from the lancet (see [0088]). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device of Marshall by modifying the cap of the pre-cocked version so that it was attached to the outer walls of the housing in a manner resisting forward movement of the lancet relative to the housing as taught by Koike in order to provide a more secure shipping configuration and to avoid the cap accidentally coming off before desired.

In reference to Claims 2 and 16

Marshall in view of Koike teaches the device of claims 1 and 15 (see above) and Koike teaches the at least one locating member and the at least one cooperating feature are fitted together via a groove cooperating with a flange or a rib (see Fig. 16,

the "locating member" is the groove in 12 between 12 and 22" and the cooperating feature is flange 15).

9. Claims 3, 9, 13, 14, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koike or Marshall in view of Koike (as applicable) as applied to claims 1, 2, or 17 (as applicable) above, and further in view of US Pat. No. 3,165,220 to Haynes ("Haynes").

In reference to Claims 3, 13, 17, and 18

Marshall in view of Koike teaches the device of claims 1 and 15 (see above). Koike teaches the device of claim 11 (see above). However, neither Marshall nor Koike explicitly teach two flanges fitting into grooves in two opposed sides of outer walls of the housing or that the head of the cap can be rotated 90 degrees to release flanges from notches in two sides of the housing (see Fig. 5, a 90 degree rotation would release the flanges from the notches). Haynes teaches a tamper-proof container enclosure in which the cap includes two flanges (**34**) while the container includes grooves (**18**). The device includes frangible buttons/pins **28** which when broken, indicate that the original seal has been broken (see col. 1 line 60 – col. 2 line 60). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device of Koike or Marshall in view of Koike by including a tamper-proof enclosure using flanges, grooves, and pins as taught by Haynes, in the sealed cap taught by Koike, so the user could know whether the device was previously opened as taught by Haynes.

In reference to Claim 9

Marshall in view of Koike and Haynes teaches the device of claim 3 (see above), and Marshall further teaches the lancet is spring-loaded to urge the lancet in the direction towards the opening in the housing (via 7, see Fig. 1).

In reference to Claims 14 and 19

Marshall in view of Koike and Haynes teaches the device of claims 13 and 18 (see above) and Marshall further teaches the lancet can move forward until a ledge (23) on the lancet locates against a flange (12) on a trigger member.

Response to Arguments

10. Applicant's arguments filed 9/7/2010 have been fully considered but they are not persuasive. In response to Applicant's arguments (pgs. 12-13 of Remarks) that "it is clear that this arrangement of cap/stem in Figure 16 of KOIKE does not prevent forward movement of the lancet and certainly not against the force of the drive spring", the Examiner respectfully disagrees. It is noted that, as detailed in the rejections above, the Examiner contends that the arrangement of cap/stem in Figs. 16 and 18 of Koike do prevent forward movement of the lancet, as Koike discloses that the cap is attached to the housing in a manner that the cap must be twisted and pulled to release the cap, and this attachment force would at least prevent some forward movement of the lancet, and because the embodiment of Fig. 18 discloses that the attachment of the cap to the housing is such that when a force is applied to the lancet to move it partially forward to contact the cap, the cap remains attached to the housing and must be twisted and pulled to remove it (as detailed in Figs. 18A-C and [0102]).

11. In response to Applicant's arguments (pg. 13 of Remarks) that Koike does not disclose "at least one locating member fitting into at least one cooperating feature of the outer walls of the housing", the Examiner respectfully disagrees for the reasons detailed in the Office Action of 5/4/2010.

12. In response to Applicant's arguments (pg. 13 of Remarks) that Koike does not disclose "the cap to be twistable to release the locating member from the cooperating feature", the Examiner respectfully disagrees, as Koike clearly discloses that the cap is twisted and pulled to remove it from the housing as detailed above.

13. In response to Applicant's arguments (pg. 14 of Remarks) that "these functions are unexpected in light of KOIKE", the Examiner respectfully disagrees and notes that this is merely argument, and no evidence is provided that these functions are unexpected relative to Koike.

14. In response to Applicant's arguments (pg. 14 of Remarks) that "the cap does not engage releasably with the housing to hold the spring in the compressed position", it is noted that this limitation is not found in the claims.

15. In response to Applicant's arguments that "there is no suggestion whatsoever in KOIKE that this arrangement would prevent forward movement of the lancet", the Examiner notes that this language is functional language, and that in addition to previously mentioned rationale suggesting that this arrangement would prevent forward movement, the language is functional language, and the cap could be interpreted as preventing forward movement by preventing a user from grasping the lancet and pulling it forward.

16. In response to Applicant's assertions that Marshall teaches away from a pre-cocked device, the Examiner respectfully disagrees, as Marshall explicitly contemplates this configuration in col. 2 lines 44-51.

17. In response to Applicant's arguments that Marshall does not disclose a cap "adapted to hold the lancet in a position in which the lancet latch surface is spaced rearwardly of the latch surface of said trigger-releasable latch until said cap is detached from the lancet", the Examiner respectfully disagrees, for the reasons detailed in the rejection above (note that the interpretation has been clarified).

18. In response to Applicant's arguments that it would not have been obvious to combine the teachings of Koike or Marshall with Haynes, the Examiner respectfully disagrees, for the reasons detailed in the rejection above and those previously mentioned in the Office Action of 5/4/10.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JP/ 10/20/10

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736